#### THIRTY-SEVENTH MEETING

# NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

**September 15, 2000** 

# National Institutes of Health Bethesda, Maryland

### **MINUTES**

The National Deafness and Other Communication Disorders Advisory Council convened for its thirty-seventh meeting on September 15, 2000, in Conference Room C, Neurosciences Center, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Open: September 15, 2000: 8:30 a.m. to 12:30 p.m., for the review and discussion of program development, needs and policy; and

Closed: September 15, 2000: 12:30 p.m. to 2:30 p.m. for review of individual grant applications.

Council members present:<sup>1</sup>

Dr. Rita S. Berndt

Dr. Gail D. Burd

Dr. Bernard Cohen

Dr. David P. Corey

Dr. Judy R. Dubno

Dr. Beverly Emanuel

Dr. Bernard Harris

Dr. Ronald R. Hoy

Dr. Jacqueline E. Jones

Dr. Nicolas Linares-Orama

Mr. John Madison

Dr. Miriam H. Meisler

Ms. Donna L. Sorkin

Ms. Virginia W. Stern

Dr. Orlando Taylor

Dr. Ingo Titze

Dr. Gregory T. Wolf

Council member absent:

Ms. Rebecca Dresser

1For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

### Ex-Officio Members present:

Dr. Lucille B. Beck

Ex-Officio Members absent:

Dr. John R. Franks Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed his appreciation to all Council members for their service and advice to the Institute. Dr. Battey welcomed and introduced four new members of Council:

- Beverly S. Emanuel, Ph.D., is Professor of Pediatrics with Tenure, and Professor of Pediatrics in Human Genetics at the University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania. Dr. Emanuel received her doctoral degree in microbiology from the University of Pennsylvania Graduate School of Arts and Sciences. Her current research includes cytogenetic and molecular studies of human chromosome 22 and velocardiofacial syndrome.
- <u>Nicolas Linares-Orama, Ph.D.</u> is on the faculty of the College of Health-Related Professions at the University of Puerto Rico. Dr. Linares-Orama received his doctoral degree in Speech and Hearing Science from the University of Illinois In 1975. His research expertise focuses on Hispanic children with childhood autism; developmental assessment; and the association of language-learning disabilities with juvenile delinquency.
- Ingo Titze, Ph.D. is on the faculty of the University of Iowa Foundation in the
  Departments of Speech Pathology and Audiology, where he is also a Distinguished
  Professor in the School of Music. Dr. Titze received his doctoral degree in physics
  from Brigham Young University. His current research includes stimulation of voice
  qualities in speech and biomechanics of the larynx.
- John P. Madison, Ed.D. is an Associate Professor in the Department of English, at the National Technical Institute for the Deaf, in Rochester, New York. Dr. Madison received his Ed.D. in Curriculum /Elementary Education from the University of Illinois, Urbana, Illinois. His current activities include writing various publications relating to language arts and science for hearing-impaired children.

### II. Council Procedures ...... Dr. Craig A. Jordan

### Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members avoiding conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be open to the public during the morning session, but would be closed for consideration of grant applications during the afternoon.

### Consideration of Minutes from the Meeting of May 24, 2000

Dr. Battey called members' attention to the Minutes of the Council's meeting of May 24, 2000. The minutes were approved as written, with one minor editorial change to the roster.

### Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2002 have been established. A list of these meetings was distributed to the Council members. The next meeting of Council is scheduled for Friday, January 26, 2001 on the NIH campus, Bethesda, Maryland.

# III. Report of the Director, NIDCD ...... Dr. Battey

### **Budget Considerations**

Without an approved FY2001 budget, Dr. Battey's presentation was predicated upon the tentative Senate appropriation figures. Dr. Battey discussed how the nearly \$55.2 million available for new and competing research project grants will be allocated in FY2001. After consideration of pre-existing commitments, and equally distributing funds across the three Councils, approximately \$15.9 million is available for the September Council. Twenty percent of this (\$3.2 million) will be designated for High Program Priority. This leaves approximately \$12.7 million available for the initial payline, which should allow funding of applications to the 30th percentile. A copy of the slide Dr. Battey used for his budget presentation is included in these Minutes as Appendix 3.

### IV. Report of the Director, Division of Extramural Research ........... Dr. Robert Dobie

### New Investigators

The NIDCD definition of "new principal investigator (PI)" is based on two criteria:

- Less than 10 years following the terminal degree (clinical training years are not counted against this 10-year period).
- No prior R01 or R29, as P.I.

There was discussion by Council that this definition might exclude individuals who wished to make mid-career transitions to research after relatively long periods in teaching or clinical practice. Dr. Battey indicated that the Institute would consider a flexible approach in determining such individuals' eligibility. Such an approach would require staff to determine whether an individual PI had had "substantial" research support from sources other than NIH; the required information is often not available in the grant application. This would allow such individuals to take full benefit of NIDCD policies/practices designed to assist new PIs. For purposes of tracking the Institute's success in increasing the number of funded new PIs, the simple NIDCD definition permits classification based on information readily available to staff. While it may require special consideration for a few individuals, such as those described above, it will reliably track trends over time.

### Staff Recruitment

Dr. Dobie reported that Dr. Barry Davis has been selected as a Health Scientist Administrator in the Scientific Programs Branch. He has primary responsibility for the portfolio of taste grants. Recruitment is underway to fill the Health Scientist Administrator positions left vacant by Dr. Beth Ansel and Dr. Rochelle Small, both of whom accepted positions in other Institutes. The recent retirement of Ms. Sharon Hunt, Chief of the Grants Management Branch, has led to a recruitment process to identify her replacement as well. Dr. Dobie encouraged Council's participation in disseminating information about these recruitments.

#### NIDCD Initial Review:

In response to Dr. Battey's request, Dr. Luecke and Dr. Dobie recently assembled a group of DER staff to begin a process to evaluate the Institute's review activities. The group assembled for the purpose of open discussion as a initial effort of defining the goals and process of the evaluation.

Several issues were discussed:

 What are the proper roles for standing committees (such as CDRC) vs. special emphasis panels (SEPS)?

- Does CDRC have adequate representation of expertise across the scientific areas of NIDCD? Should it be expanded again?
- Should NIDCD have more than one standing committee, or form subcommittees within CDRC?
- Should review groups be defined by grant mechanism (K, P, etc.); mission area (auditory, chemical senses, language, etc.; or level of analysis (cellular/molecular, integrative, clinical)?
- Should the group that finally is formed to study and report on these issues include people from other NIH Institutes or Centers, from the extramural research community, or other communities?

After this initial meeting, Dr. Jordan prepared a description of how reviews are conducted within NIDCD. He is surveying review colleagues across NIH for descriptions of their institute's review structures/practices. A future meeting will consider the additional materials and help plan the process to be used for this review activity.

#### 

In accordance with recommendations from the NIDCD Study Group on R&D Contracts and Other Special Initiatives, the Work Group on Concept Clearance (WGCC) was established to provide concept clearance for Institute initiatives that would require set-aside funds (RFP's, RFA's and PAS's). The WGCC will meet in open session three times a year, generally in the afternoon of the day preceding regularly scheduled NDCD Advisory Council meetings, to provide concept clearance for possible research initiatives. Dr. Craig Jordan will coordinate these activities and serves as executive secretary to the work group.

The WGCC is comprised of three Advisory Council members, one of whom serves as Chair, plus one member from the NIDCD Board of Scientific Counselors (BSC). Additional (ad hoc) members will be identified as needed. The terms of service for members of the WGCC coincide with their terms as Advisory Council or BSC members.

Potential initiatives (both new and renewal) will be presented by NIDCD staff to the WGCC. In advance of the meeting, the executive secretary provides the WGCC with a one-page description of the proposed initiative and, as appropriate, back-up materials from earlier feasibility considerations. Following a brief presentation by the staff member proposing the initiative and Qs and As, the WGCC will address five issues:

- significance of the initiative to the mission of the NIDCD;
- availability of the technology and other resources necessary to achieve the required goals (i.e., can the initiative be accomplished?):
- scientific or clinical utility of the initiative;
- when relevant, the likelihood that the proposed methodology will accomplish

the goals of the initiative;

• adequacy of inclusion of women and minorities in clinical research, if applicable.

Favorably recommended concept initiatives, which are slated for set-aside funding, will be noted by the Division Directors in their presentations to the Advisory Council.

Current WGCC membership includes Council members Dr. Gail Burd, Chair; Dr. David Corey, Dr. Gregory Wolf and Board of Scientific Counselors member Dr. Randall Reed.

### 

Dr. Daniel Sklare, Scientific Programs Branch, Division of Extramural Research, presented a summary of recent developments in the NIDCD Extramural Research Training and Career Development Program. These developments were catalyzed by recommendations made to the Institute by the Work Group on Research Training and Career Development, held on December 8-9, 1999. A dissertation-stage individual predoctoral fellowship (F31) program has been inaugurated in collaboration with four other NIH Institutes. Predoctoral and postdoctoral fellowship applications received by the NIDCD (with the exception of the those responding to the NIH-wide F31 programs for underrepresented minority students and students with disabilities) are now reviewed by the NIDCD Scientific Review Branch rather than by the NIH Center for Scientific Review; this facilitates an expedited submission-to-award schedule of four months. The new provisions to the NIDCD mentored clinician-investigator (K-series) awards were presented. The augmentation of the NIDCD Small Grant (R03) to serve a career development purpose was underscored.

# VII. "Cochlear Implants – Past, Present And Future "......Dr. Richard Miyamoto

Dr. Battey introduced Dr. Richard Miyamoto, a former member of the NDCD Advisory Council, and Arilla Spence Devoult Professor and Chairman of the Department of Otolaryngology-HNS, at Indiana University, School of Medicine. Dr. Miyamoto discussed his exciting research on cochlear implants. Following is an abstract of Dr. Miyamoto's presentation:

## <u>COCHLEAR IMPLANTS – PAST, PRESENT AND FUTURE</u>

The electrically generated sensation of hearing has been extensively studied since Djourno and Eyries first described direct excitation of the auditory nerve in 1957. Devices of increasing sophistication have secured a permanent role for cochlear implants in the management of selected severely and profoundly deaf children and adults. Cochlear implants seek to replace a nonfunctional inner-ear hair cell transducer system by converting mechanical sound energy into electrical signals that can be delivered to the cochlear nerve in profoundly deaf patients. The signals are introduced through a surgically implanted electrode array positioned in the cochlea.

The full impact of cochlear implants can be documented only through detailed longitudinal studies. A trend toward earlier cochlear implantation in children has emerged in an attempt to ameliorate the devastating effects of early auditory deprivation. A wide range of performance is seen with current implant systems. This performance variation is thought to relate to both biologic and cognitive abilities. Patients are able to reestablish environmental contact and enhance their speech-reading abilities and many cochlear implant patients can communicate without the benefit of lip reading.

Improvements in speech perception are the most direct benefit of cochlear implantation. However, if children with cochlear implants are to succeed in the hearing world, they must also acquire intelligible speech. The most successful pediatric cochlear implant users are demonstrating intelligible speech and age appropriate language skills. These superior performers are usually implanted at a young age and are educated in an oral/aural modality.

### 

NIH policy requires that the National Advisory Council to each Institute review the activities of their respective intramural program once a year. Dr. Robert Wenthold, Scientific Director of NIDCD's Division of Intramural Research (DIR), presented the report.

He began his report by introducing Dr. David Robinson, who was recently appointed as Deputy Scientific Director. Dr. Wenthold announced that two investigators have accepted tenure track positions in the DIR. They are Dr. Doris Wu, formerly a Research Fellow with the NIDCD; and Dr. Matthew Kelley, formerly Assistant Professor, Department of Cell Biology, Georgetown University. Dr. Andrew Griffith has also been recruited for a tenure track position. Dr. Wenthold summarized the academic background and research interests of each of these investigators.

The Intramural Research Program currently consists of six tenured scientists and seven tenure track scientists, three in the clinical track and four in the basic science track. Dr. Wenthold closed his report with a discussion of the membership and responsibilities of the Board of Scientific Counselors

### **CLOSED SESSION**

## IX. Report of the Board of Scientific Counselors ......Dr. Battey

Dr. Battey presented the Report of the Board of Scientific Counselors (BSC). As stipulated by law, each Institute, Center or Division must provide annually to its National Advisory Council an overview of its intramural research program. The overview should include the reports of the BSC, and the responses of the Scientific Director. This presentation is strictly informational; Council members are not asked to recommend approval or disapproval of the reports or to modify them in any way. However, the Council

may make recommendations to the Director, NIDCD regarding such research on the basis of the materials provided.

[Executive Secretary Note: During the BSC presentation, attendance was restricted to the Council members, the Director, NIDCD; the Deputy Director, NIDCD; the Director, Division of Extramural Research, NIDCD; and the Executive Secretary of the Council.]

### X. Council Consideration of Pending Applications

The Council gave special attention to applications from foreign institutions and to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or minority and gender representation in study populations as identified by the initial review groups.

### A. Research Project Grant Awards

Consideration of Applications: On the Council's agenda was a total of 120 research grant applications; 86 applications had primary assignment to NIDCD, in the amount of \$18.5 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to applications scoring through the 30th percentile.

### **B.** Special Programs Actions

- 1. <u>Small Business Innovation Research Awards (SBIR).</u> The Council recommended support for six Phase I (R43) and six Phase II (R44) applications.
- 2. <u>Small Business Technology Transfer (STTR):</u> The Council recommended support for one Phase II (R42) application.
- 3. <u>Small Grants (R03):</u> The Council recommended support for thirteen applications.
- 4. <u>Academic Research Enhancement Awards (R15)</u>: The Council recommended support for one application.
- 5. Research Core Centers (P30): The Council recommended support for three applications.
- 6. <u>Clinical Research Center Grant (P50)</u>: The Council recommended support for one application.
- 7. <u>Intervention Strategies Following the Early Identification of Hearing Impairment (PAS-99-011) (R01):</u> The Council recommended support for two applications.

- 8. <u>NIDCD Minority Dissertation Research Grants in Human Communication (RFA-DC00-001)</u> (R03): The Council recommended support for four applications.
- 9. <u>Exploratory Developmental Grants RFA MH00-002 (R21)</u>: The Council recommended support for one application.
- 10. <u>Impact of HAART on HIV/CNS Disease (RFA MH00-003) (R01):</u> The Council recommended support for two applications.

### D. <u>Career Development Programs</u>

- Independent Scientist Award (K02): The Council recommended support for one application.
- 2. <u>Mentored Clinical Scientist Development Award (K08):</u> The Council recommended support for one application.
- 3. <u>Mentored Patient-Oriented Research Award (K23):</u> The Council recommended support for one application.
- 4. <u>Midcareer Investigator Award in Patient-Oriented Research (K24)</u>: The Council recommended support for one application.
- X. Adjournment: The meeting was adjourned at 2:15 p.m. on September 15, 2000.

accurate and correct. <sup>2</sup>	f our knowledge, the foregoing minutes and attachments are
	Craig A. Jordan, Ph.D. Executive Secretary National Deafness and Other Communication Disorders Advisory Council
	James F. Battey, Jr., M.D., Ph.D. Chairman National Deafness and Other Communication Disorders Advisory Council
Jeannie Combs	Director National Institute on Deafness and Other Communication Disorders
Council Assistant	
2 These minutes will be formally con minutes of that meeting.	sidered by the Council at its next meeting; corrections or notations will be incorporated in t

he

# **APPENDICES**

		PAGE
APPENDIX 1	NDCD Advisory Council Roster	11
APPENDIX 2	List of Meeting Attendees	13
APPENDIX 3	Budget Considerations (Dr. Battey)	16

# Appendix 1

# Roster

National Deafness and Other Communication Disorders Advisory Council

# Chairperson

Battey, James F., Jr., M.D., Ph.D.

Director

National Institute on Deafness and Other Communication Disorders

Bethesda, Maryland 20892

BERNDT, Rita S., Ph.D. Professor Department of Neurology University of Maryland School of Medicine Baltimore, Maryland	2002	DRESSER, Rebecca S., J.D. Professor, School of Law and Program for the Humanities in Medicir Washington University School of Law St. Louis, Missouri	2001 ne
BURD, Gail D., Ph.D. Professor and Associate Department Head Molecular and Cellular Biology University of Arizona	2003	DUBNO, Judy R., Ph.D. Professor Department of Otolaryngology- Head and Neck Surgery Medical University of South Carolina Charleston, SC	2003
Tucson, Arizona  COHEN, Bernard, M.D.  Morris B. Bender Professor of Neurology Department of Neurology Mount Sinai School of Medicine City University of New York	2002	EMANUEL, Beverly S., Ph.D. The Charles E.H.Upham Professor of Ped University of Pennsylvania School of Med Chief, Division of Human Genetics and Molecular Biology The Children's Hospital of Philadelphia Philadelphia, PA	
New York, New York  COREY, David P., Ph.D.  Professor of Neurobiology  Harvard Medical School  Neurobiologist, Department of Neurobiolo	2001 niology	HARRIS, Bernard A., Jr., M.D. Vice President Microgravity and Life Science SPACEHAB, Inc. Houston, Texas	2002
Massachusetts General Hospital Boston, Massachusetts		HOY, Ronald R., Ph.D. Professor Section of Neurobiology and Behavior Cornell University	2003

Ithaca, New York

JONES, Jacqueline E., M.D.	2002	Ex-Officio Members:
Associate Professor of Clinical Otolaryngology Cornell University Medical College		BECK, Lucille B., Ph.D. Director
New York, New York		Audiology and Speech Pathology Service
LINARES-ORAMA, Nicolas, Ph.D. University of Puerto Rico Medical Sciences Campus	2004	Department of Veterans Affairs Washington, D.C.
San Juan, Puerto Rico		FRANKS, John R., Ph.D. Chief, Bioacoustics and Occupational
MADISON, John P., Ed.D. Associate Professor	2004	Vibration Section Physical Agent Effects Branch
Department of English National Technical Institute for the Deaf Rochester, NY		Division of Biomedical and Behavioral Science National Institute for Occupational Safety and Health
MEISLER, Miriam H., Ph.D.	2003	Cincinnati, Ohio
Professor Human Genetics Department School of Medicine University of Michigan Ann Arbor, Michigan		HOFFER, Michael E., M.D. Department of Otolaryngology Naval Medical Center San Diego, California
SORKIN, Donna L.	2002	SHALALA, Donna E., Ph.D. Secretary
Alexander Graham Bell Association for the Deaf and Hard of Hearing Washington, DC	2002	Department of Health and Human Services Washington, D.C.
STERN, Virginia W. American Association for the	2001	KIRSCHSTEIN, Ruth L., M.D. Acting Director
Advancement of Science Washington, D.C.		National Institutes of Health Bethesda, Maryland
TAYLOR, Orlando L., Ph.D. Dean	2001	EXECUTIVE SECRETARY
Graduate School of Arts & Sciences Howard University Washington, D.C.		JORDAN, Craig A., Ph.D. Executive Secretary
TITZE, Ingo R., Ph.D.	2004	Division of Extramural Activities, NIDCD Bethesda, Maryland
Department of Speech Pathology and Audiology University of Iowa Iowa City, IA	2001	Boulocaa, Marylana
WOLF, Gregory T., M.D. Chair, Department of Otolaryngology- Head and Neck Surgery University of Michigan Medical Center Ann Arbor, Michigan	2001	

### **Appendix 2**

#### ATTENDANCE LIST

Other than Council members, attendees at the September 2000 Council meeting included:

### NIDCD Staff:

### Office of the Director

Luecke, Donald H., M.D., Deputy Director Phillips, Isabelle, Secretary Lopez, Joyce, Program Specialist

### Office of Administration

Kerr, W. David, Executive Officer

### Financial Management Branch

Sparks, Patience, Budget Officer

### <u>Information Systems Management Branch</u>

Hamilton, Sue, Chief

### Science Policy and Legislation Branch

Smith, Mary, Acting Chief Wong, Baldwin, Program Analyst

### **Equal Employment Opportunities Branch**

Johnson-Graham, Kay, EEO Officer

#### Division of Extramural Research

Dobie, Robert A., M.D., Director Combs, Jeannie, Program Analyst DaSilva, Maria, Program Assistant Holmes, Debbie, Secretary Stephenson, Nanette, Program Assistant

#### Grants Management Branch

Hunt, Sharon, Chief Chicchirichi, David, Grants Management Specialist Dabney, Sherry, Grants Management Officer McNamara, Castilla, Grants Management Specialist Ranney, Meigs, Grants Management Officer

### Scientific Programs Branch

Cooper, Judith, Ph.D., Chief; and Program Director, Language Davis, Barry, Ph.D., Program Director, Taste/Gustation

Small, Rochelle, Ph.D., Program Director, Smell/Olfaction Gulya, Julie, M.D., Program Director, Clinical Trials

### Hearing and Balance/Vestibular Section

Donahue, Amy, Chief; and Program Director, Hearing Freeman, Nancy, Ph.D., Program Director, Hearing Johnson, Thomas, Ph.D., Program Director, Hearing Luethke, Lynn, Ph.D., Program Director, Hearing Sklare, Daniel A., Ph.D., Program Director, Balance/Vestibular

#### Scientific Review Branch

Jordan, Craig A., Ph.D., Chief Oaks, Stanley C., Ph.D., Scientific Review Administrator Stick, Melissa J., Ph.D., M.P.H., Scientific Review Administrator

#### Division of Extramural Research

Wenthold, Robert, M.D., Scientific Director Robinson, David, M.D., Deputy Scientific Director

### Center for Scientific Review, NIH

Kimm, Joseph, Ph.D., Scientific Review Administrator Kenshalo, Daniel, Ph.D., Scientific Review Administrator Meadow-Orlans, Kathryn, Ph.D., Scientific Review Administrator Sostek-Miller, Anita, Ph.D., Scientific Review Administrator Melchior, Christine, Ph.D., Scientific Review Administrator

### Others

Moss, Sharon, Ph.D., American Speech and Hearing Association Stone, Alec, Ph.D., Deafness Research Foundation

# Appendix 3

# **NIDCD Director's Report Slides**

As Presented By James F. Battey, Jr., M.D., Ph.D. NDCD Advisory Council Meeting

September 15, 2000

